ATTORNEY DOCKET NO. 14014.0410U1
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Strober, Warren	)	Art Unit: 1644
	)	
Application No. 10/517,898	)	Examiner: Ouspenski, Ilia I.
	)	
Int. Filing Date: June 14, 2002	)	Confirmation No. 5707
	)	
For: METHODS OF TREATING AND PREVENTING COLITIS INVOLVING IL-13 AND NK-T CELLS	)	

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BALLARD SPAHR ANDREWS & INGERSOLL, LLP
Customer Number 36339

Sir:

This is in response to the Office Action dated September 11, 2008, wherein restriction of the claims of the above-identified application is required. A Request for Extension of time is included herewith.

The Office Action requires restriction to one of the following six groups of claims:

Group I: Claims 38-49, 52-62, and 65-71, drawn to a method of treating or preventing an inflammatory response of colitis by administering an antibody that binds to Cd1;

Group II: Claims 38-48, 52-61, and 63-71, drawn to a method of treating or preventing an inflammatory response of colitis by administering an antibody that binds to Vα 14 Jα 281 or Vα 24 Jα 18;

Group III: Claims 38-48, 50-61, and 65-72, drawn to a method of treating or preventing an inflammatory response of colitis by administering IL-13α Ra2-Fc;

Group IV: Claims 38-48, 52-61, 65-71 and 73, drawn to a method of treating or preventing an inflammatory response of colitis by administering an antibody that binds to IL-13;

Group V: Claims 38-48, 52-61, 65-71 and 74, drawn to a method of treating or preventing an inflammatory response of colitis by administering an antibody that binds to IL-13αRα2 [sic]; and

Group VI: Claims 75-84, drawn to a method of screening a substance for effectiveness in reducing the inflammatory response to colitis.

As required in response to the Restriction Requirement, Applicants provisionally elect Group IV (claims 38-48, 52-61, 65-71 and 73) with traverse.

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. The Examiner proposes that the groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1. According to the Office action, the inventions of Groups I-VI are deemed to have no special technical feature that defines the contribution over the prior art of US Patent No. 6,696,545 ('545). The Office posits that this patent teaches a peptide for use in inhibiting the production of inflammatory cytokines, such as IL-13, for inhibiting inflammatory response in colitis. Applicants respectfully disagree.

The '545 patent indicates that the peptides disclosed therein are capable of inhibiting the cellular production of inflammatory cytokines. The '545 patent proceeds to list several exemplary inflammatory cytokines, including IL-12 and IL-13 (column 10, lines 54-57). The '545 patent then lists several inflammatory responses that can be treated using the disclosed peptides, including Crohn's disease and colitis (column 10, lines 63-65). There is no indication

in '545, however, which of the cytokines are relevant to each of the listed inflammatory conditions. This combination is therefore neither explicit nor enabled.

It is legal error to infer a combination from a genus of targets and a genus of diseases to arrive at a disclosure that overcomes the special technical feature. The Office is therefore using impermissible hindsight to suggest that the skilled artisan would have known IL-13 could be targeted in order to treat either Crohn's disease or colitis.

In fact, the '545 patent states "the subject peptides will find use in ... inhibition of inflammatory responses that are associated with a variety of disorders ... and numerous other situations where an anti-inflammatory response is desired" (column 10, lines 59-65; emphasis added). The '545 patent is therefore relying on knowledge in the art to guide the skilled artisan to select the appropriate cytokine inhibitor for the selected inflammatory disease. This reliance does not therefore enable any specific combination, including the use of an IL-13 inhibitor to treat Crohn's disease or colitis. Absent a more explicit teaching in a prior art reference, the Office has not met its burden of challenging unity of invention based on the special technical feature that defines the contribution over the prior art.

Applicants also traverse the restriction requirement as currently set forth for the following reasons. To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. M.P.E.P. § 803 provides:

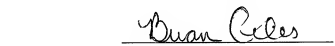
> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added.*)

Applicants note that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the "inventions" would overly burden the Examiner. Accordingly, for this additional reason, there is no basis for maintaining the restriction requirement.

Moreover, Applicants respectfully assert that restriction of the claims as set forth by the Examiner would be contrary to promoting efficiency, economy and expediency in the Patent Office and further point out that restriction by the Examiner is discretionary (M.P.E.P. § 803.01). Thus, Applicants respectfully request that all of the claims of this application be examined together. Consequently, reconsideration and modification or withdrawal of the restriction requirement is requested.

It is believed that no fee is due with this submission. However, the Commissioner is hereby authorized to charge any fees which may be required to Deposit Account No. 14-0629.

Respectfully submitted,



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